

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2216642	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Urologic Institute Of The High Desert, Inc	Street Address, City, State 72-650 Fred Waring Dr Ste 208, Palm Desert, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, and interview with the Laboratory Director (DL) on February 11, 2026, the laboratory failed to verify the accuracy of histopathology and NON-GYN cytology testing at least twice annually. In addition, the laboratory failed to achieve satisfactory performance for the subspecialty of bacteriology in two out of three consecutive testing events for the analyte Mycoplasma genitalium. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for bacteriology testing in 2025. According to the API evaluation record, the laboratory attained scores of 50% in the subspecialty of bacteriology for the analyte Mycoplasma genitalium during the second PT event of 2025 (Q2/2025) and 0% during the third PT event of 2025 (Q3/2025). 2. The laboratory started testing in the specialty histopathology and non-GYN cytology in January 2025, which are not listed in subpart I of 42 CFR part 493. For the test procedure not listed in subpart I, the laboratory must verify the accuracy of the test procedure twice annually. The laboratory did not have any record for accuracy verification in 2025. 3. On February 11, 2026, at approximately 10:30 am, the laboratory director affirmed receiving unsatisfactory proficiency scores for Mycoplasma genitalium. The laboratory director also confirmed that the laboratory did not verify the accuracy of histopathology and non-GYN cytology at least twice in 2025. 4. The laboratory's testing declaration form, signed by the laboratory director on February 11, 2026, stated that the laboratory performed approximately 41800 microbiology tests including Mycoplasma genitalium and 1300 pathology testing including histopathology and cytology.</p>

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory's proficiency testing (PT) records, and interview with the Laboratory Director (DL) on February 11, 2026, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings included: 1. It was the practice of the laboratory to perform histopathology and non-GYN cytology testing, which are not listed in subpart I of the 42 CFR part 493. For test procedure not listed in subpart I, the laboratory must verify the accuracy of the test procedure at least twice annually. 2. The laboratory director failed to ensure that the laboratory had policies and procedures in place to verify the accuracy of these tests twice annually. Consequently, no accuracy verification was performed twice annually as required. See D5217